Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in August 2015.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-442

Trade Name:	LUTALYSE® HighCon Injection
Ingredients:	Dinoprost tromethamine
Sponsor:	Zoetis Inc.
Approval Date:	August 17, 2015
Status:	Rx
Route:	Intramuscular injection
Species:	Lactating dairy cows, beef cows, beef heifers, and replacement dairy heifers
Drug Form:	Injectable solution
Concentration:	12.5 mg dinoprost/mL as dinoprost tromethamine
Indications:	For estrus synchronization in beef cows, beef heifers and replacement dairy heifers; for unobserved (silent) estrus in lactating dairy cows with a corpus luteum; for treatment of pyometra (chronic endometritis) in cattle; for abortion of beef cows, beef heifers and replacement dairy heifers; for use with FACTREL (gonadorelin injection) Injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows; for use with EAZI-BREED CIDR (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in lactating dairy cows; and for use with EAZI-BREED CIDR (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers.
Exclusivity:	3 years
Patent:	Patent Number 6,187,818 — Expiration date: June 17, 2018

NADA Number: 141-443

Trade Name:	onsior®
Ingredients:	Robenacoxib
Sponsor:	Novartis Animal Health US, Inc.
Approval Date:	August 5, 2015
Status:	Rx
Route:	Subcutaneous injection
Species:	Cats
Drug Form:	Injection
Concentration:	20 mg/mL
Indications:	For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats ≥ 4 months of age; for up to a maximum of 3 days.
Exclusivity:	3 years
Patent:	Patent Number 6,291,523 — Expiration date: August 25, 2018 Patent Number 6,310,099 — Expiration date: August 25, 2018

ANADA Number: 200-583

Trade Name:	Actogain™ 45 plus Rumensin® plus Tylovet® 100 plus MGA®
Pioneer:	Optaflexx™ plus Rumensin® plus Tylan® plus MGA®
Ingredients:	Ractopamine hydrochloride, monensin USP, tylosin phosphate, and melengestrol acetate
Sponsor:	Zoetis Inc.
Approval Date:	August 24, 2015
Status:	OTC
Route:	Oral, in feed

Species:	Heifers fed in confinement for slaughter
Drug Form:	Type A medicated articles
Concentration:	Ractopamine hydrochloride - 45.4 g/lb Monensin USP - 90.7 g/lb Tylosin phosphate - 100 g/lb Melengestrol acetate - 200 (dry) and 500 (liquid) mg/lb
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.

ANADA Number: 200-584

Trade Name:	Engain™ plus Tylovet® 100
Pioneer:	Paylean® plus Tylan® plus
Ingredients:	Ractopamine hydrochloride and tylosin phosphate
Sponsor:	Zoetis Inc.
Approval Date:	August 24, 2015
Status:	OTC
Route:	Oral, in feed
Species:	Finishing Swine
Drug Form:	Type A medicated articles
Concentration:	Ractopamine hydrochloride - 9 g/lb Tylosin phosphate - 100 g/lb
Indications:	Ractopamine hydrochloride (4.5 to 9.0 g/ton) in combination with tylosin phosphate 100 g/ton - For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*. Ractopamine hydrochloride (4.5 to 9.0 g/ton) in combination with tylosin phosphate (40 or 100 g/ton) - For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; for control of swine dysentery associated with *Brachyspira hyodysenteriae*; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*. Ractopamine hydrochloride (4.5 to 9.0 g/ton) in combination with tylosin phosphate (40 to 100 g/ton) - For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; for treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae*; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

ANADA Number: 200-585

Trade Name:	Actogain™ 45 plus Rumensin® plus Tylovet® 100
Pioneer:	Optaflexx™ plus Rumensin® plus Tylan®
Ingredients:	Ractopamine hydrochloride, monensin USP, and tylosin phosphate
Sponsor:	Zoetis Inc.
Approval Date:	August 24, 2015
Status:	OTC
Route:	Oral, in feed
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A medicated articles
Concentration:	Ractopamine hydrochloride - 45.4 g/lb Monensin USP - 90.7 g/lb Tylosin phosphate - 100 g/lb

Indications: Ractopamine hydrochloride (8.2 to 24.6 g/ton) in combination with monensin USP (10 to 40 g/ton) and tylosin phosphate (8 to 10 g/ton) - For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (Actinomyces) pyogenes in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.

Ractopamine hydrochloride (9.8 to 24.6 g/ton) in combination with monensin USP (10 to 40 g/ton) and tylosin phosphate (8 to 10 g/ton) - For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *E. bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.

Ractopamine hydrochloride top dress (not to exceed 800 g/ton) plus monensin USP (10 to 40 g/ton) in combination with tylosin phosphate (8 to 10 g/ton) - For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *E. bovis* and *E. zuernii* and reduction in incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-509

Trade Name: Tilmovet® 90
Ingredients: Tilmicosin
Sponsor: Huvepharma AD
Approval Date: August 27, 2015

This supplement provides for addition of the following indication for use in a new species/class: "For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in groups of beef and non-lactating dairy cattle, where active BRD has been diagnosed in at least 10% of the animals in the group."

Sponsor Address Change

Sponsor: Pharmgate LLC

New Address: 1015 Ashes Drive, Suite 102
Wilmington, NC 28405

Patent Revision

NADA Number: 141-320

Patent number: 6,291,523
Previous Expiration Date: September 18, 2018
Revised Expiration Date: August 25, 2018